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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/078,805

02/18/2002

James S. Stefely

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10/09/2007

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

10/09/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	Application No. 10/078,805	Applicant(s) STEFELY ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 42,44-52,55 and 57-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42,44-51,55,67,72-77 and 79-87 is/are rejected.
- 7) ☒ Claim(s) 52,57-66,68-71 and 78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1616

A consensus was reached at a patentability conference held 9/27/07 that prosecution be reopened.

Claims 42, 44-52, 55, 57-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 42 (c) "biocompatible polymer comprises at least one chain of units of the formula . . . " is vague because it is unclear, for example, in the case of one chain of the recited formula, as to what makes up the remainder of the polymer.

In claim 42 (a) and (b) following the formula, "catenary nitrogen" is indefinite. Applicants do not define the meaning of the term. It could mean a central nitrogen from which hang two chains of some undefined length and composition. It could also mean that the nitrogen is part of a chain.

In claims 42, 46, 81-82, "substantially completely" is vague because "substantially" is subjective.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42, 44-51, 55, 67, 72-77, 79-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patton.

Art Unit: 1616

Patton teaches a composition comprising parathyroid hormone fragments as a dry powder in an aerosol propellant suitable for use in a metered dose inhaler (abstract). 34 and 38 amino acid fragments are disclosed (column 4 lines 41-42). Human serum albumin is disclosed as a 1-10% bulking powder (column 5 lines 41-47). Chlorofluorocarbon propellants are specified (column 6 lines 17-23). Ethanol is specified (column 6 lines 26-29). 1-25% active is disclosed (column 6 lines 64-65). A pulsatile concentration profile is specified, delivery in by patient acceptable pathway, namely by respiratory delivery (column 2 lines 1-15).

It would have been obvious to one of ordinary skill to make a composition comprising parathyroid fragments delivered by a metered dose inhaler to achieve the beneficial effect of a pulsatile concentration profile by a patient acceptable delivery method. As to the claimed amount of of polymer and ratio of polymer to active, Patton teaches suitable ranges of active and polymer are provided. Optimum suitable amounts may be obtained by routine experimentation, absent a showing of unexpected results. As to the claimed polydispersity, it is argued that the molecular weight of albumin is under genetic control, well within the claimed limits. As to the claimed increase of therapeutic activity with versus without the polymer, such must be possessed by the obvious composition because it is the same as that claimed.

Claims 42, 44-51, 55, 67, 72-77, 79-87 are rejected.

Art Unit: 1616

Claims 52, 57-66, 68-71, 78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
EDWARD J. WEBMAN  
PATENT EXAMINER  
GROUP 1600